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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,377	02/08/2002	Gert Hobom	100727-14 /Kreisler 1094-	5110

27384 7590 04/20/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,377	HOBOM ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *12-29 and 31-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30 in the scope of SEQ ID NO: 4, 5, 10, 45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence letter*.

DETAILED ACTION

Claims 1-47 are pending.

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-11 and 30 in the scope of SEQ ID NO: 4, 5, 10, 45 and 46 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that group IV, V and VI that read on the process should be rejoined with the product claims of group I if the group I is found to be allowable.

2. Applicants' argument has been respectfully considered; however, the rejoining groups IV-VI with group I will not be considered at the present because at the present the product of the group I has not been found in allowable condition.

3. Applicants are reminded that where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

4. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the

prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. The requirement is still deemed proper and is therefore made FINAL.

6. Claims 1-11 and 30 are considered.

7. Claims 12-29 and 31-47 are withdraw from the consideration.

Sequence requirements

8. This application contains sequence disclosures on **pages 15, 16, 29 and 45** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

9. Full compliance with the sequence rules by **inserting a corresponding SEQ ID No** is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Specification

10. The disclosure is objected to because of the following confusing recitation on lines 12-15 of page 12: *In the present application "human influenza virus" includes all types of non-avian influenza viruses, including human, equine and porcine influenza viruses and the like, with human influenza viruses being the proffered ones.*

11. It is so confused in that how equine and porcine influenza viruses are classified into human influenza virus. Appropriate clarification and correction are required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-11 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claims 1 and 3 are indefinite for using a relative word " at least". Since there is no given upper limitation of mutated amino acid residues in the said claims, the claims are considered as indefinite. This affects the dependent claims 2-11 and 30.

15. Regarding claim 2, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

16. Claim 4 is unclear in that the metes and bounds of " five distinguishing amino acids" are not defined. Please specify which " five distinguishing amino acids" are referred in the claim.

17. The claim 6 is also vague for recitation of a relative word "capable of", because the capability of a compound or composition to perform some function is merely a statement of a latent characteristic of said compound or composition and said language carries no patentable weight. Therefore, the claims are regarded as indefinite.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-2, 3, 4, 6, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a chimeric virus comprising replacement of the cording sequence of RNA-polymerase of the wilt-type human influenza virus type H1N1, WSN/33 strain with that of flow plague virus or with three nucleotide mutations at the positions of G3A, C8U and U5C of the 3' terminal promoter region that appear in the FPV sequence,

resulting in a virus with an enhanced transcription and replication characteristic, does not reasonably provide enablement for having a chimeric virus made by any or all at least one of the amino acid residues replacement with FPV in the region of RNA polymerase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

20. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

21. 1) & 2) State of Art and Unpredictability of the field. The state of art teaches that a recombinant virus with a chimeric promoter region comprising three nucleotide mutations including G3A, U5C and C8U at the 3' RNA promoter regions. The resulting chimeric virus can produce an enhanced transcription and replication activity. However, it is unpredictable for only having one or two such kind of mutation. For example, Neumann et al. (J. Gene. Virol. 1995, Vol. 76, pp. 1709-1717) teach that single nucleotide exchange abolished the promoter cavity. Two of the double mutation constructs gave negative results (See page 17).

22. 3) & Number of working examples and guidance in the specification. Applicants only teach a chimeric influenza virus made by replacing the RNA polymerase region of human influenza virus WSN-PB1 region with the corresponding region of FPV or substituting three nucleotides of G3A, U5C and C8U from the 3' terminus, wherein the chimeric virus is able to produce an enhanced transcription and replication properties. Applicants present no working examples of any other chimeric virus or guidance for making any or all chimeric virus as it is claimed.

23. 5) Scope of the claims. The claims broadly read on a chimeric human influenza virus made by any or all human influenza virus and FPV, in that at least any nucleotide exchange or amino acid exchange will produce a chimeric that is able to produce an enhanced transcription and replication.

24. 6) & 7) Nature of the invention and Lever of the skill in the art. The invention involves one of the most complex and unpredictable field of making a chimeric virus by a high technique of molecule biology at the PhD level.

25. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 112

26. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

27. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

28. In the instant case, the disclosure of current applicants has only disclosed the chimeric influenza virus comprising a promoter-up sequence made by substituting the amino acid residue(s) in the PB1 region of human influenza virus A type H1N1, WSN/33 strain with the corresponding amino acid residue (s) of flow plague virus (FPV) in the same region, resulting in an enhanced rate of transcription and/or replication relative to the wild-type human influenza virus, The sequence of the modified PB1 region in the chimeric human influenza A/FPV is encoded by SEQ ID NOs: 45 in protein and 46 in RNA. However, the specification does not have the possession for having other chimeric virus made by other influenza virus, such as PR8/34, influenza A type H2N2 including Asia/57 or like or influenza A type H3N2 including Victoria/68 or like. There is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed chimeric virus sequence. Therefore, a written description of the other claimed chimeric virus should be disclosed to overcome this

rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that "a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention". Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular product because it gives detailed information on how to produce an analogous but it makes no reference to the product in question, the "written description" requirement has not been met even though the description may be enabling.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

30. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

31. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. Claims 1, 2, 6, 7, 8, 9, 10 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,524,588B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 of patent "588" is drawn to an influenza virus comprising a mutations at the 3' and 5' terminal promoter regions, wherein the 3' terminal nucleotides sequence is modified by replacement of three nucleotides naturally occurring at the position 3, 5, and 8 by other influenza virus, resulting in enhanced rate of transcription, replication or expression compared with the wild-type influenza virus. The three replacements in the 3' terminal nucleotide sequence consisting of G3A, C8U and C8U. The 3' terminal nucleotide sequence is 5'-CCUGUUUCUAC-3' (SEQ ID NO: 9). While the claims "588" do not same such modification is done by replacing the nucleotides of human influenza virus with influenza A/flow plague virus (FPV)/Brastislava, the modified virus does have the same mutations and 3' nucleotide sequence to the one as it is claimed in the current application. Moreover, the specification of patent "588" teach that the mutated virus is produced by co-infecting a host cell B82 with human influenza virus strain pHL1104 and influenza A/flow plague virus (FPV)/Brastislava (See lines 36 on col. 12). Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated in light of the disclosure of Patent "588" to make a mutated influenza virus by replacing the nucleotide of the human influenza virus with that of influenza A/flow plague virus (FPV)/Brastislava by the same substitution as it is disclosed in Patent "588" absence of unexpected result.

33. Claims 1, 6, 7, 8, 9, 10 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 6, 7, 8, 9, 10, 12 of copending Application No. 09, 914,658.

34. In the instant case, both application 09/914,658 and current application are drawn to a recombinant influenza virus comprising a mutations at the 3' and 5' terminal promoter regions, wherein the 3' terminal nucleotides sequence is modified by replacement of three nucleotides naturally occurring at the position 3, 5, and 8 by other influenza virus, resulting in enhanced rate of transcription, replication or expression compared with the wild-type influenza virus. The three replacements in the 3' terminal nucleotide sequence consisting of G3A, C8U and C8U. The 3'

terminal nucleotide sequence is 5'-CCUGUUUCUAC-3' (SEQ ID NO: 9). While the claims "588" do not same such modification is done by replacing the nucleotides of human influenza virus with influenza A/flow plague virus (FPV)/Brastislava, the modified viruses are produced by the same method as disclosed in the current application of the same mutations and the three substitutive mutations are the same as it ~~is~~ they are claimed in the current application. Therefore, the claimed invention is rejected under obviousness double patenting.

35. This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

36. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

37. Claims 1-11 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Hobom et al. (US patent No. 6,524,588B1)

38. The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

39. Patent "588" is drawn to an influenza virus comprising a mutations at the 3' and 5' terminal promoter regions, wherein the 3' terminal nucleotides sequence is modified by replacement of three nucleotides naturally occurring at the position 3, 5, and 8 by other influenza virus, resulting in enhanced rate of transcription, replication or expression compared with the

wild-type influenza virus. The three replacements in the 3' terminal nucleotide sequence consisting of G3A, C8U and C8U. The 3' terminal nucleotide sequence is 5'-CCUGUUUCUAC-3' (SEQ ID NO: 9). While the claims "588" do not same such modification is done by replacing the nucleotides of human influenza virus with influenza A/flow plague virus (FPV)/Brastislava, the modified virus does have the same mutations and 3' nucleotide sequence to the one as it is claimed in the current application. Moreover, the specification of patent "588" teach that the mutated virus is produced by co-infecting a host cell B82 with human influenza virus strain pHL1104 and influenza A/flow plague virus (FPV)/Brastislava (See lines 36 on col. 12). Therefore, the influenza virus of patent "588' is inherently modified by replacing the nucleotides in human influenza virus with that of avian influenza A/FPV/Brastislava. Therefore, the claims are anticipated by the cited reference.

Claim Rejections - 35 USC § 102

40. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

41. Claims 1, 3, 6, 7, 8, 9, 10, 11 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Hobom et al. (EP 1174514A1) or Schuler et al. (EP 1 202,760A1).

42. Both prior art are directed to a recombinant influenza virus and a composition comprising a mutated influenza virus having a same mutation at the 3' terminal sequence modification as it is claimed in the current application although prior art does not teach that replaced regular nucleotides of the human influenza virus are from flow plague virus (FPV). These three replacements at the 3' terminus are G3A, U5C, and C8U, or G3C, U5C and C8G, and the 3' terminal has the sequence of (5')-CCUGUUUCUACU-3', and the 5' terminal nucleotide sequence comprises the modification U3A and A8U resulting in a 5'-terminal sequence of 5'-AGAAGAAUCAAGG. All of these modifications result in improved transcription rates of both the vRNA promoter as well as the cRNA promoter (See Hobom et al. at claims 1, 7-13 and 20.

See Schuler at al. at line 36 on page 5 to line 40 on page 6). Therefore, the claimed invention is anticipated by the cited reference.

43. Claims 1, 2, 3, 6, 7, 8 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Flick et al. (J. Gene. Virol. 1999, Vol. 80, pp. 2565-2572).

44. Flick et al. disclose a recombinant chimeric influenza virus produced by a plasmid comprising promoter-up variant having three mutation of G3A, U5C and C8U at the 3' terminus and other influenza virus genome. The chimeric virus further comprises a CAT cDNA flanked by influenza virus promoter-up variant. While Neumann et al. do not explicitly point out that the expressed influenza virus is a human influenza virus comprises FPV virus substitutive mutations, the recombinant virus was made by human influenza virus and influenza virus strain A/FPV/Bratislava. More specifically, the three substitutive mutations at the position 3, 5, and 8 that are presented in the influenza virus strain A/FPV/Bratislava .

45. Moreover, the definition of the "human influenza virus" is interpreted in the specification as a "vector", " expression vector" or "virus vector". The recombinant influenza virus expressed by the disclosed expressing plasmid is a expressing vector carrying a reporter gene of CAT or green fluorescent protein (GFP). Hence, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

46. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

47. Claims 1, 2, 3, 6, 7, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Neumann et al. (J. Gene. Virol. 1995, Vol. 76, pp. 1079-1717).

48. Neumann et al. teach a chimeric influenza virus construct comprising the mutated vRNA and/or mutated cRNA promoter sequences that are derived from a plasmid pHL926. The promoter region of the virus comprises one to three mutation at the position 3, 5 and 8 from the 3' terminus. The construct of the chimeric virus further comprises a CAT cDNA with flanking

non-coding sequences derived from influenza virus vRNA segment. The construct containing three nucleotide exchanges at G3A, C8U, U5C is able to produce an enhanced transcription and replication activities (See page 1711). While Neumann et al. do not explicitly teach that the plasmid pHL926 encoding a genome from human influenza virus and the chimeric mutation comprises FPV virus substitutive mutations, the pHL926 encodes a human influenza virus genome in light of the teaching by Zobel et al. (Nucleic Acids Research 1993 Vol. 21, No. 16, pp. 3607-3614). The recombinant virus was made by human influenza virus and influenza virus strain A/FPV/Bratislava. Therefore, the resulting virus comprising one to three substitutive mutations at the position 3, 5, and 8 that are appears in the influenza virus strain A/FPV/Bratislava, which are the same mutation as it is claimed in the current application (Claim 8-9).

49. Regarding to the limitation of human influenza virus as it is claimed, because the definition of the "human influenza virus" is also interpreted in the specification as a "vector", " expression vector" or "virus vector". Neumann et al. disclose the recombinant influenza virus as a recombinant influenza virus expressed by an expressing plasmid construct, which comprises a mutated vRNA and/or mutated cRNA promoter sequence of influenza promoter regions derived from human influenza virus and a CAT reporter gene inserted into the coding sequence of influenza virus HA region. The recombinant virus is generated by first transfecting the host B82 cells with the plasmid described above and further infected with the influenza virus strain A/FPV/Bratislava. The resulting virus therefore, contains the substitutive mutation with the nucleic acids appeared in the influenza virus strain A/FPV/Bratislava Hence, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James C. Housel 4/19/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Bao Qun Li
Art Unit 1648.
April 05, 2004